

Message Text

UNCLASSIFIED

PAGE 01 PARIS 18975 281654Z
ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 L-03 OES-07 COME-00 EB-07
/036 W

-----113653 282006Z /75

R 281648Z JUN 77
FM AMEMBASSY PARIS
TO SECSTATE WASHDC 4887

UNCLAS PARIS 18975

E.O. 11652: N/A
TAGS: OGEN, ETRD, EIND, TBIO, FR
SUBJECT: FDA ADVISORY - RECALL OF IMPLANTABLE DEMAND
TYPE PACEMAKERS (RECALL T-069/072-7)

REF.: STATE 135023

1. MR. ALAIN BOUQUET, DIRECTOR OF MEDICATH ELECTRONICS,
98 RUE BARRAULT, 750L3 PARIS, WHICH DISTRIBUTES
PACEMAKERS MANUFACTURED BY AMERICAN TECHNOLOGY INC.,
19749 BAHAMA ST., NORTHRIDGE, CA. (PHONE 213- 882 -
8770) WAS CONTACTED BY POST CONCERNING SUBJECT RECALL.

2. MR. BOUQUET WAS AWARE OF RECALL BUT REQUESTED
APPOINTMENT TO DISCUSS MATTER FURTHER.

3. HE WAS CONCERNED ABOUT HIS POTENTIAL LIABILITY IF
SUED BY DOCTORS WHO HAD IMPLANTED THESE PACEMAKERS
IN PATIENTS, THEN REMOVED THEM DUE TO RECALL. HE WAS
ALSO CONCERNED ABOUT RECOUPING LOSSES OF SOME
\$ 100,000 FOR EQUIPMENT SOLD. HE HOPES TO BE REIMBURSED
BY MANUFACTURER FOR DEVICES ALREADY RETURNED TO THEM,
BUT WOULD STILL LOSE HIS COMMISSION. HE HAS ALREADY
REIMBURSED HIS CLIENTS.

4. POST ADVISED MR. BOUQUET TO SEEK LEGAL ADVICE.
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INFORMATION PROVIDED SINCE SUIT COULD HAVE ADVERSE
REPERCUSSIONS BEYOND THE FIRMS DIRECTLY INVOLVED
DEPENDING ON AMOUNT OF PUBLICITY.
GAMMON.

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, FOOD & DRUG REGULATIONS, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 28-Jun-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977PARIS18975
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Document Unique ID: 00
Drafter: n/a
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Executive Order: N/A
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ISecure: 1
Legacy Key: link1977/newtext/t19770611/aaaaajaw.tel
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Litigation History:
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Original Previous Classification: n/a
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To: STATE
Type: TE
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